

# **EXHIBIT 2**



Centers for Disease Control and Prevention  
CDC 24/7: Saving Lives, Protecting People™

## Coronavirus Disease 2019 (COVID-19)

# Strategies for Optimizing the Supply of N95 Respirators

### Related Pages

[N95 Respirator Summary](#)

[Stockpiled N95 Respirators](#)

Updated April 2, 2020

### Summary of Updates as of April 2, 2020:

- [Conventional capacity strategies](#)
  - Edited the section on use of airborne infection isolation rooms (AIIRs) for aerosol-generating procedures performed on patients with confirmed or suspected COVID-19 patients.
  - Added language on FDA's Emergency Use Authorization (EUA) authorizing the use of certain NIOSH-approved respirator models in healthcare settings to the section on N95 alternatives.
- [Contingency capacity strategies](#)
  - Added a section on temporarily suspending annual fit testing following updated guidance from OSHA
  - Added more details in the extended use section.
- [Crisis capacity strategies](#)
  - Added language on the use of respirators approved under international standards and updated the tables.
  - Combined sections on limited re-use of N95 respirators for tuberculosis and then COVID-19 patients. Added more details surrounding limited re-use.

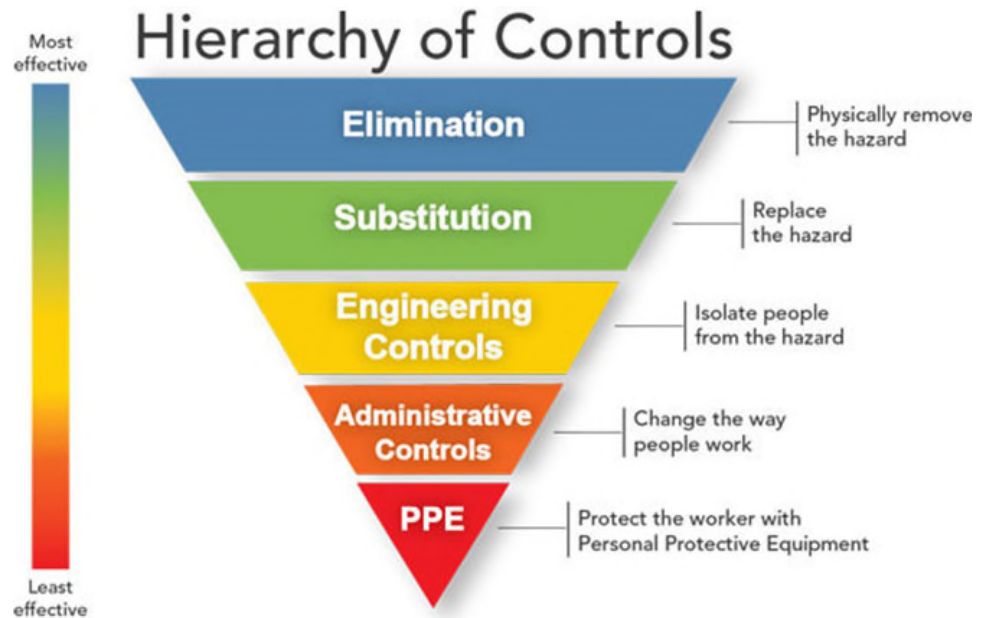
**Audience:** These considerations are intended for use by federal, state, and local public health officials, respiratory protection program managers, leaders in occupational health services and infection prevention and control programs, and other leaders in healthcare settings who are responsible for developing and implementing policies and procedures for preventing pathogen transmission in healthcare settings.

**Purpose:** This document offers a series of strategies or options to optimize supplies of disposable N95 filtering facepiece respirators (commonly called "N95 respirators") in healthcare settings when there is limited supply. It does not address other aspects of pandemic planning; for those, healthcare facilities can refer to [COVID-19 preparedness plans](#). The strategies are also listed in order of priority and preference in the [Checklist for Healthcare Facilities: Strategies for Optimizing the Supply of N95 Respirators during the COVID-19 Response](#) in an easy-to-use format for healthcare facilities.

Controlling exposures to occupational hazards is a fundamental way to protect

personnel. Conventionally, a hierarchy has been used to achieve feasible and effective controls. Multiple control strategies can be implemented concurrently and or sequentially. This hierarchy can be represented as follows:

- Elimination
- Substitution
- Engineering controls
- Administrative controls
- Personal protective equipment (PPE)



To prevent infectious disease transmission, elimination

(physically removing the hazard) and substitution (replacing the hazard) are not typically options for healthcare settings. However, exposures to transmissible respiratory pathogens in healthcare facilities can often be reduced or possibly avoided through engineering and administrative controls and PPE. Prompt detection and effective triage and isolation of potentially infectious patients are essential to prevent unnecessary exposures among patients, healthcare personnel (HCP), and visitors at the facility.

N95 respirators are the PPE most often used to control exposures to infections transmitted via the airborne route, though their effectiveness is highly dependent upon proper fit and use. The optimal way to prevent airborne transmission is to use a combination of interventions from across the hierarchy of controls, not just PPE alone. Applying a combination of controls can provide an additional degree of protection, even if one intervention fails or is not available.

Respirators, when required to protect HCP from airborne contaminants such as some infectious agents, must be used in the context of a comprehensive, written respiratory protection program that meets the requirements of [OSHA's Respiratory Protection standard](#) [\[link\]](#). The program should include medical evaluations, training, and fit testing.

Surge capacity refers to the ability to manage a sudden, unexpected increase in patient volume that would otherwise severely challenge or exceed the present capacity of a facility. While there are no commonly accepted measurements or triggers to distinguish surge capacity from daily patient care capacity, surge capacity is a useful framework to approach a decreased supply of N95 respirators during the COVID-19 response. Three general strata have been used to describe surge capacity and can be used to prioritize measures to conserve N95 respirator supplies along the continuum of care.<sup>1</sup>

- **Conventional capacity:** measures consist of providing patient care without any change in daily contemporary practices. This set of measures, consisting of engineering, administrative, and PPE controls should already be implemented in general infection prevention and control plans in healthcare settings.
- **Contingency capacity:** measures may change daily standard practices but may not have any significant impact on the care delivered to the patient or the safety of HCP. These practices may be used temporarily during periods of expected N95 respirator shortages.
- **Crisis capacity:** strategies that are not commensurate with U.S. standards of care. These measures, or a combination of these measures, may need to be considered during periods of known N95 respirator shortages.

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**Conventional Capacity Strategies (should be incorporated into everyday practices)**

## Engineering Controls

**Engineering controls** reduce exposures for HCP by placing a barrier between the hazard and the HCP. Engineering controls can be very effective as part of a suite of strategies to protect HCP without placing primary responsibility of implementation on them (i.e., they function without HCP having to take an action).

Selective use of airborne infection isolation rooms

Use of physical barriers

Properly maintained ventilation systems

## Administrative Controls

**Administrative controls** are employer-dictated work practices and policies that reduce or prevent hazardous exposures. Their effectiveness depends on employer commitment and HCP acceptance and consistent use of the strategies.

Limit number of patients going to hospital or outpatient settings

Telemedicine

Exclude all HCP not directly involved in patient care

Limit face-to-face HCP encounters with patient

Exclude visitors to patients with known or suspected COVID-19

Source control

Cohorting patients

Cohorting HCP

Training on indications for use of N95 respirators

Training on use of N95 respirators

Just-in-time fit testing

Limiting respirators during training

Qualitative fit testing

## Personal Protective Equipment: Respiratory Protection

While engineering and administrative controls should be considered first when selecting controls, the use of **personal protective equipment (PPE)** should also be part of a suite of strategies used to protect personnel. Proper use of respiratory protection by HCP requires a comprehensive program (including medical clearance, training, and fit testing) that complies with [OSHA's Respiratory Protection Standard](#) and a high level of HCP involvement and commitment. The program should also include provisions for the cleaning, disinfecting, inspection, repair, and storage of respirators used by HCP on the job according to manufacturer's instructions. Proper storage conditions can

maximize shelf life of respirators. The following strategies in this section are traditionally used by some healthcare systems. If not already implemented, these strategies can be considered by healthcare settings in the face of a potential N95 respirator shortage before implementing the contingency strategies that are listed further below.

## N95 respirators

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### Use of alternatives to N95 respirators

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## Contingency Capacity Strategies (during expected shortages)

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Decisions to implement contingency are based upon these assumptions:

1. Facilities understand their current N95 respirator inventory and supply chain
2. Facilities understand their N95 respirator [utilization rate](#)
3. Facilities are in communication with local healthcare coalitions, federal, state, and local public health partners (e.g., public health emergency preparedness and response staff) regarding identification of additional supplies
4. Facilities have already implemented [conventional capacity measures](#)
5. Facilities have provided HCP with required education and training, including having them demonstrate competency with donning and doffing, with any PPE ensemble that is used to perform job responsibilities, such as provision of patient care

## Administrative Controls

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### Decrease length of hospital stay for medically stable patients with COVID-19

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### Temporarily suspend annual fit testing

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## Personal Protective Equipment: Respiratory Protection

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### Use of N95 respirators beyond the manufacturer-designated shelf life for training and fit testing

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### Extended use of N95 respirators

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## Crisis Capacity Strategies (during known shortages)

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Decisions to implement crisis strategies are based upon these assumptions:

1. Facilities understand their current N95 respirator inventory and supply chain
2. Facilities understand their N95 respirator [utilization rate](#)
3. Facilities are in communication with local healthcare coalitions, federal, state, and local public health partners (e.g., public health emergency preparedness and response staff) regarding identification of additional supplies
4. Facilities have already implemented [contingency capacity measures](#)
5. Facilities have provided HCP with required education and training, including having them demonstrate competency with donning and doffing, with any PPE ensemble that is used to perform job responsibilities, such as provision of patient care

## When N95 Supplies are Running Low

### Personal Protective Equipment: Respiratory Protection and Facemasks

Use of respirators beyond the manufacturer-designated shelf life for healthcare delivery

Use of respirators approved under standards used in other countries that are similar to NIOSH-approved respirators

Limited re-use of N95 respirators

Use of additional respirators beyond the manufacturer-designated shelf life for healthcare delivery that have not been evaluated by NIOSH

Prioritize the use of N95 respirators and facemasks by activity type

## When No Respirators are Left

### Administrative Controls

Exclude HCP at higher risk for severe illness from COVID-19 from contact with known or suspected COVID-19 patients

Designate convalescent HCP for provision of care to known or suspected COVID-19 patients

### Engineering Controls

Expedient patient isolation rooms for risk-reduction

Ventilated Headboards

## References

- <sup>1</sup> Hick JL, Barbera JA, Kelen GD. Refining surge capacity: conventional, contingency, and crisis capacity. *Disaster Med Public Health Prep.* 2009;3(2 Suppl): S59-67.
- <sup>2</sup> Bergman, MS, Viscusi DJ, Zhuang Z, Palmiero AJ, Powell JB, Shaffer RE. Impact of multiple consecutive donnings on filtering facepiece respirator fit. *Am J Infect Control.* 2012;40(4): 375-380.
- <sup>3</sup> van Doremalen N, Bushmaker T, Morris DH. Aerosol and Surface Stability of SARS-CoV-2 as Compared with SARS-CoV-1. *N Engl J Med.* 2020 Mar 17.
- <sup>4</sup> Dato, VM, Hostler, D, and Hahn, ME. Simple Respiratory Mask, *Emerg Infect Dis.* 2006; 12(6): 1033–1034
- <sup>5</sup> Rengasamy S, Eimer B, and Shaffer R. Simple respiratory protection-evaluation of the filtration performance of cloth masks and common fabric materials against 20-1000 nm size particles, [Ann Occup Hyg.](#) 2010;54(7):789-98.